## REMARKS

Claim 24 is the only claim that remains in the application. Claim 24 has been amended to clarify that the T cell response is specific to influenza. Support for this amendment can be found in paragraph [0068] as well as in Examples 2-4 showing that the T cell response is specific to influenza in immunized mice. The term "vaccine agent" has also been defined according to paragraph [0051]. No new matter has been added.

Claim 24 stands rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 5,614,504 to Hadden, et al. Specifically, the Office Action holds that Hadden, et al. discloses a method of enhancing the immune response to a vaccine comprising administering an adjuvant formulation comprising inosine 5'-monophosphate compounds, including MIMP, administering the IMP compounds to treat influenza, measuring a response to the vaccine, and measuring an enhanced DTH response and T cell activation and cytokine secretion in response to IMP compounds. In response to previous arguments, the Office Action holds that squalene is used in vaccines as part of an adjuvant formulation and can be considered a "vaccine agent" as recited in the instant claims. The Office Action further holds that Hadden, et al. teaches that after administration of viral vaccine combined with an IMP compound, proliferation assays in response to viral antigen can be performed in order to determine if the subject has been successfully immunized, it is well established that T cells proliferate in response to antigen stimulation in successfully immunized subjects, and the method would inherently measure T cells proliferating specifically to the viral antigen. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Hadden, et al, as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

Hadden, et al. does not disclose the combination of an IMP with an influenza vaccine in order to treat influenza. Example 10 in Hadden, et al. shows that mice challenged with influenza virus were administered MIMP or Squalene, which is merely an excipient in formulation, plus MIMP. Squalene is not an influenza vaccine. Hadden, et al. only discloses administering the IMP compound itself in treating various conditions, including influenza.

In contradistinction, the present invention according to currently amended independent claim 24 requires the presence of an influenza vaccine. The agent enhances the effect that the IMP compound has on the influenza as compared to administering the IMP compound alone. Applicants note that squalene as defined in the present application is an adjuvant, but not a vaccine agent (see paragraph [0054]), nor is squalene an influenza vaccine. A vaccine agent refers to proteins, peptides, coat proteins, viral coats, viruses, bacteria, antigen, whole cells, cell components, parasites, pathogens, and any other vaccine agent known to those of skill in the art, as described in paragraph [0051]. Thus, a vaccine agent does not encompass squalene.

Furthermore, while Hadden, et al. describes a general T cell stimulation when IMP compounds are applied to cells, such as in Example 2 and Example 3, ***Hadden, et al. does not show a T cell response specific to influenza*** but rather only that mice given MIMP increased mean survival time in Example 10. Therefore, Hadden, et al. cannot perform the step of detecting a T cell response specific to influenza with respect to a treatment for influenza. One cannot assume that a T cell response is present in an unhealthy subject that cannot mount an immune response normally just because a T cell response has been observed in healthy, normal cells.

The present invention shows a T cell response for the first time in influenza challenged mice, as shown in Examples 2-4. MIMP is administered in combination with an influenza vaccine in Example 4. Without having shown that IMP provides a T cell response specifically to influenza, and without having administered an influenza vaccine, Hadden, et al. cannot disclose the method of the present invention.

Therefore, since Hadden, et al. does not disclose IMP in combination with an influenza vaccine or detecting a T cell response in influenza as set forth in the presently pending independent claims, the claims are patentable over Hadden, et al. and reconsideration of the rejection is respectfully requested.

Claim 24 stands rejected under 35 U.S.C. §112, first paragraph, for containing new matter for the limitation of detecting a "T cell response specific to influenza". Specifically, the Office Action holds that the claim is not limited to administering an influenza vaccine but broadly encompasses any vaccine agent, antiviral agent, or antimicrobial agent. In response thereto, in order to conform the language of the claim with the step of detecting a T cell response specific to influenza, the claim has been amended to recite that an influenza vaccine is administered in combination with the MIMP. Support can be found for this amendment in Figure 12 and in Example 4. Reconsideration of the rejection is respectfully requested.

In conclusion, it is respectfully requested that the present amendment be entered in order to place the application in condition for allowance, which allowance is respectfully requested.

All required fees for the three extensions have been paid via credit card concurrent with filing this response.

Respectfully submitted,

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**CERTIFICATE OF ELECTRONIC FILING VIA EFS-WEB**

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I hereby certify that this correspondence is being electronically filed with the United States Patent & trademark Office on the above date.

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